

Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Sundee Agrawal, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2379, Silver Spring, MD 20993–0002, 301–348–3914; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.” This guidance provides recommendations to sponsors regarding the development of drugs regulated by Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research for the adjuvant treatment of muscle-invasive bladder cancer. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of muscle-invasive bladder cancer, this guidance is focused on cancer trials with DFS as the primary efficacy endpoint.

Adjuvant muscle-invasive bladder cancer clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA–National Cancer Institute public workshop held on November 28, 2017. This guidance provides recommendations on these issues to facilitate adjuvant muscle-invasive bladder cancer clinical trials. This guidance finalizes the draft guidance entitled “Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment: issued on October 1, 2020 (85 FR 62309). FDA considered comments received on the draft guidance as the guidance was finalized.

The final guidance includes changes to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: June 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; U24 ATLAS Applications.

Date: July 29, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard Bethesda, MD 20892–2542, 301–594–4721, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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